

(f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of vitamin C deficiency which was the purpose for which it was intended as claimed in the label statement "Provides therapeutic doses of ascorbic acid for the correction of vitamin C deficiency."

DISPOSITION: 4-25-60. McKesson & Robbins, Inc., claimant, having consented to the entry of a decree without admitting the alleged misbranding, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling.

6170. Cough medicine. (F.D.C. No. 44230. S. No. 64-428 P.)

QUANTITY: 415 cases, 12 2-oz. btls. each, at Stamford, Conn.

SHIPPED: Between 2-16-59 and 3-11-59, from Long Island City, N.Y., by Denver Chemical Mfg. Co.

LABEL IN PART: (Btl) "Dr. Hand's Cough Medicine For Children For Coughs Due to Colds Each 30 cc contains: Hyoscyamus alkaloids .06 mg. Sodium Bromide USP .4 gm. Sanguinaria Fluidextract, Ipecac Fluidextract USP, Tolu Balsam Tincture USP, Menthol USP, Alcohol 4% * * * Hand Medicine Co., Inc., New York, N.Y. Successors to D. B. Hand, M.D. * * * 60 cc."

ACCOMPANYING LABELING: (Leaflet in ctn.) "Today's Answer to Children's Coughs Due to Colds Dr. Hand's Cough Medicine for Children."

LIBELED: 2-10-60, Dist. Conn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for coughs due to virus and bacterial infections; tonsillitis; pharyngitis; laryngitis; tracheitis; and bronchitis; 502(f) (1)—the labeling of the article failed to bear adequate directions for use since it provided for unsupervised administration to infants and small children; and 502(f) (2)—the article failed to bear adequate warnings against use since the labeling failed to warn that the article should not be taken by persons with a high fever or persistent cough unless directed by a physician; that the article was not to be used by elderly persons or by children under six (6) years of age unless directed by a physician; that the recommended dosage should not be exceeded; that if dryness of the mouth occurred dosage should be decreased; and that one should discontinue use if rapid pulse, dizziness, or blurring of vision occurred.

DISPOSITION: 6-17-60. Default—destruction.

6171. Australian Tea Tree Oil and herbal preparations. (F.D.C. No. 44189. S. Nos. 90-802 P, 90-816/9 P.)

QUANTITY: 35 2-oz. btls. of *Australian Tea Tree Oil*; 11 3-oz. boxes and 1 bulk bag containing about 4,800 tablets, and 15 100-tablet btls. of *Compound Herb Tea Formula No. KA 13*, 22 4-oz. boxes and 1 bag containing about 9,800 tablets of *Compound Herb Tea Formula No. SL 15*, at Quincy, Mass., in possession of Puregrade Health Products, Inc.

SHIPPED: Between 4-17-59 and 9-9-59, from outside the State of Massachusetts.

LABEL IN PART: (Btl.) "Australian Tea Tree Oil (100%) For use as a Mild Antiseptic * * * Distributed by Puregrade Health Products, Inc., 25 School Street, Quincy 69, Mass."; (box) "Compound Herb Tea Formula No. KA 13 Puregrade Health Products, Inc., Quincy 69, Mass. * * * Active Ingredients: Eucalyptus Leaves, Lemon Balm Herb, Holly Leaves, Red Poppy Flowers,

Linden Flowers and Leaves, Licorice Root, Buckthorn Bark, Calendula Petals"; (btl.) "Herbal Tablet Formula KA 13 Prepared for Pure Grade Health Products, Inc. * * * Caution * * * Active Ingredients * * * Directions"; (box) "Compound Herb Tea Formula No. SL 15 Puregrade Health Products, Inc., Quincy 69, Mass. Net Weight: 4 Oz. * * * Active Ingredients: Senna Leaves, Fennel Seed, Buckthorn Bark, Licorice Root, Bladderwrack, Sweet Orange Peel, Matte, Malva Flowers, Cyani Petals, Mexican Saffron, Calendula Petals. * * *"; (bulk bag) "Formula #SL 15 Contents: Senna Leaves, Buckthorn Bark, Bladderwrack, Fennel Seed, Licorice Root, Sweet Orange Peel, Matte. Directions * * * Use: Laxative * * * Caution."

ACCOMPANYING LABELING: Leaflets entitled "Australian Tea Tree Oil" and "Medicinal Teas and tablets."

RESULTS OF INVESTIGATION: The articles were repacked and relabeled by the dealer from bulk stock shipped as described above. The leaflets were printed locally for the dealer.

LICENSED: 1-18-60, Dist. Mass.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the Tea Tree Oil, namely, the leaflet entitled "Australian Tea Tree Oil," contained false and misleading representations that the Tea Tree Oil was an adequate and effective treatment for healing fungus infections; perionychia; empyema; gynaecological conditions; psoriasis; impetigo; pediculosis; tinea; ringworm; athlete's foot; acute nasopharyngitis; catarrh; thrush; stomatitis; tonsillitis; sore throat; mouth ulcers; insect bites; itches; sores; wounds and abrasions; pimples; boils; carbuncles; and pyorrhea; killing typhoid bacillus; curing colitis; coryza; exposed ulcers; halitosis; gingivitis; pruritic acne; and conjunctivitis; and preventing colds; and the leaflets entitled "Medicinal Teas and Tablets" contained false and misleading representations that the Formula No. KA 13 was an adequate and effective treatment for the temporary and palliative relief of the paroxysms of asthma; and that the Formula No. SL 15 was adequate and effective for controlling weight by eliminating body wastes; and 502(f) (2)—the labeling of the Formula No. SL 15 failed to bear adequate warning against prolonged use, or use in those pathological conditions where its use may be dangerous to health.

DISPOSITION: 3-21-60. Default—destruction.

6172. Various drugs. (F.D.C. No. 44202. S. Nos. 72-946/53 P.)

QUANTITY: 2,000 individually cartoned tubes, 10 tablets each, of *Aspi-Quinine*, 8,500 individually cartoned tubes, 30 tablets each, of *Citrovit*, 800 individually cartoned btl., 40 tablets each, of *Ceferbios Metallic Therapy*, 2,000 individually cartoned btl. of *Bitter Tonio Giuliani*, 3,000 individually cartoned btl., 20 tablets each, of *Giuliani Bitter Laxative*, 250 individually cartoned 150-cc. btl. of *Gastro-Zyme*, 80 individually cartoned boxes of *Coffosil*, 80 boxes, 40 tablets each, of *Zimotris Composition*, at New York, N.Y., in possession of Italian Drugs Importing Co.

SHIPPED: The *Gastro-Zyme* was imported sometime prior to January 1957, and the other articles between 6-21-57 and 7-23-59, from Italy.

LABEL IN PART: (Ctn. & tube) "Aspi-Quinine Each Tab. Con.; Aspirin 0.40 Gm.—Quin. Hydrobromide 0.05 Gm. Indications * * * Warning"; "Citrovit * * * Citro-Alkaline Tablets with Vitamin C Gastric Antacid Dosage:"; (ctn. & btl.) "Ceferbios Metallic Therapy With Vit. B₁₂ and Folic Acid * * * Each